

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service Food and Drug Administration New York District Office 850 Third Avenue Brooklyn, NY 11232-1593

Telephone: [718] 340-7000 [EXT 5301]

WARNING LETTER

August 4, 1998

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Mr. Alan Clark President Mincing Trading Corporation 528 Ferry Street Newark, NJ 07105

Ref: 38-NYK-98

Dear Mr. Clark:

The Food and Drug Administration (FDA) has information which shows that your firm violated the Federal Food, Drug and Cosmetic Act.

On May 31, 1998 FDA sent an electronic message to your customs broker 2 of paprika must be held intact and not distributed. This product was to be examined or sampled by FDA when available. Mincing Trading Corporation or your import broker were required to provide FDA with a location and time for our examination or sample collection of the following:

Entry D77-0076543-2, Line 1-1, Paprika, Ground, Cracked, a total of bags, each 50 pounds.

Product location was not provided. Subsequently, on July 16, 1998 FDA sent a follow-up facsimile to Galaxy Customhouse Brokers concerning the

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status of the paprika from the above referenced entry. We were subsequently informed by Mr. Carlton Peterson, import manager of Mincing Trading, that the entire shipment of bags of paprika had been sold and distributed.

This action taken by your firm is in violation of 21 CFR 1.90, which requires an importer to hold an entry intact pending receipt of a "May Proceed" or "Release Notice" from the FDA. A "Release" by the U.S. Customs Service is a conditional release which merely permits you to take possession of the shipment. When other Federal agencies, such as FDA also exercise jurisdiction over a product offered for importation, their release must also be obtained before a product may be legally distributed.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice, such as seizure, injunction, or automatic detention to ensure that imported products are held intact until released by FDA. It is your responsibility, as the importer, to ensure that imported products meet all requirements of the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder.

Within fifteen (15) working days of receipt of this letter, please notify our office in writing of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the reoccurrence of the violation.

A copy of this letter, except for any confidential, personal, or commercial information will be placed on public display no earlier than fifteen (15) days after the date of this letter. Your response will be on public display with any confidential, personal or commercial information purged.

Your response should be addressed to the Food and Drug Administration, Attention: Joseph V. Sollazzo - Compliance Officer, Port Elizabeth Resident Post, 1201 Corbin Street, Port Elizabeth, New Jersey 07201 (telephone 1-732-645-2386 extension 20).

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Sincerely,

Brenda Holman

District Director

New York District Office

